K140089

510(k) SUMMARY

APR 0 8 2014

1. Date: February 28, 2014

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
South China University of Technology
Guangzhou, P.R. China 510641

3. Contact person: Joe Shia
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4. Device Name: CR3 Keyless Split Sample Cup Morphine-Oxazepam
Classification:

Product Code	CFR #	Panel
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology
JXM	21 CFR, 862.3170 Benzodiazepine Test System	Toxicology

5. Predicate Devices:
Guangzhou Wondfo Biotech Co., Ltd.
Wondfo Multi-Drug Urine Test Cup (Panel) (K130665)

6. Intended Use
CR3 Keyless Split Sample Cup Morphine-Oxazepam is a rapid test for the qualitative detection of Morphine (a drug in the opiate class) and Oxazepam(a drug in the benzodiazepine class) in human urine at a cutoff concentration of 2000ng/mL and 300ng/mL, respectively.
The tests may yield preliminary positive results even when prescription drugs including Morphine and Oxazepam are ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized cutoff concentration levels for morphine and oxazepam in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

7. Device Description
Immunochromatograph assays for Opiate and Benzodiazepines Urine Tests use a lateral flow, one step system for the qualitative detection of Morphine and Oxazepam in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes.

8. Substantial Equivalence Information

Item	Device	Predicate
Indication(s) for use	For the qualitative determination of Morphine, Oxazepam individual in human urine.	Same (but the number of drugs detected different)
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type Of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Morphine: 2000ng/ml Oxazepam: 300ng/ml	Same (but the number of drugs detected different)
Configurations	Split Keyless Cup	Cup, Dip Card
Intended Use	OTC Use & Prescription Use	Same

9. Test Principle

It is a rapid test for the qualitative detection of Morphine and Oxazepam in urine samples. It is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentration below the target cut off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cutoff, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in the test region, indicating a preliminary positive result.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100%cut off, -75%cut off, -50%cut off, -25%cut off, +25%cut off, +50%cut off , +75%cut off and +100%cut off. For each concentration, tests were performed two runs per day for 25 days with three different lots of devices. The results obtained are summarized in the following table.

A. For Morphine testing

Result / OPI	-100% cut off	-75% cut off	-50% cut off	-25% Cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
W11510201CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W11510202CU5	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
W11510203CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

B. For Oxazepam testing

Result / BZO	-100% cut off	-75% cut off	-50% cut off	-25% Cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
W11510201CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W11510202CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W11510203CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable

c. Stability

It is stable at 4-30°C for 18 months.

d. Cut-off

Test	Calibrator	Cut-off (ng/ml)
Morphine	Morphine	2000
Oxazepam	Oxazepam	300

e. Interference

Compounds that show no interference at a concentration of 100 μg/mL are summarized in the following tables.

Morphine

4-Acetamidophenol	Ecgonine methylester	Oxolinic acid
Acetophenetidin	(-) -Y -Ephedrine	Oxymetazoline
N-Acetylprocainamide	Erythromycin	Papaverine
Acetylsalicylic acid	β-Estradiol	Penicillin-G
Aminopyrine	Estrone-3-sulfate	Pentazocine
Amitryptyline	Ethyl-p-aminobenzoate	Pentobarbital
Amobarbital	Fenoprofen	Perphenazine
Amoxicillin	Furosemide	Phencyclidine

Ampicillin
Ascorbic acid
D,L-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin (±)
Brompheniramine
Caffeine
Cannabidiol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaine hydrochloride
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine hydrochloride

Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxy methamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Maprotiline
Meperidine
Meprobamate
Methadone
Methoxyphenamine
(+) 3,4-Methylenedioxy-amphetamine
(+)3,4-Methylenedioxy-methamphetamine
Nalidixic acid
Nalorphine
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam

Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
Prednisone
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3 Acetate
Tetrahydrocortisone3 (β -D glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
D, L-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D, L-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

Oxazepam

4-Acetamidophenol
Acetophenetidin
N-Acetvprocainamide
Acetvsalicvlic acid
Aminopvrine

Doxylamine
Ecaonine dydrochloride
Ecqonine methylester
(-)-Y-Ephedrine
Fenoprofen

Oxolinic acid
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine

Amityptvline	Furosemide	Phenobarbital
Amorbarbital	Gentisic acid	Phentermine
Amoxicillin	Hemoglobin	L-Phenylephrine
Ampicillin	Hydrocortisone	β-Phenylethylamine
l-Ascorbic Acid	O-Hydroxyhippuric acid	Phenylpropanotamine
D.L-Amphetamine	p-Hydroxy- methamphetamine	Prednisone
Apormorphine	3-Hydroxytyramine	D.L-Propanolol
Aspartame	Ibuprofen	D-Propoxyphene
Atropine	Imipramine	D-Pseudoephedrine
Benzillic acid	Iproniazid	Quinine
Benzoic acid	(±)Isoproterenol	Ranitidine
Benzoylecaonine	Isoxsuprine	Salicylic acid
Benzphetamine	Ketamine	Secobarbital
Bilirubin	Ketoprofen	Serotonin (5-Hydroxytyramine)
(±) Chlorpheniramine	Labetalol	Sertraline
Caffeine	Loperamide	Sulfamethazine
Cannabidiol	Maprotiline	Sulindac
Chloralhvdrate	Meperidine	Tetrahydrocortisone,3 Acetate
Chloramphenicol	Meprobamate	Tetrahydrocortisone,(β-D glucuronide)
Chlorothiazide	Methadone	Tetrahydrozoline
(±)Chlorpheniramine	Methoxyphenamine	Thiamine
Chlorpromazine	(+) 3,4-Methylenedioxy-amphetamine	Thioridazine
Chlorquine	(+)3,4-Methylenedioxy-methamphetamine	D.L-Tyrosine
Cholesterol	Nalidixic acid	Tolbutamide
Clomipramine	Nalorphine	Triamterene
Clonidine	Naloxone	Trifluoperazine
Cocaine hydrochloride	Naltrexone	Trimethoprim
Cortisone	Naproxen	Triyptamine
(-)cotinine	Niacinamide	D.L-Tryptophan
Creatinine	Nifedipine	Tyramine
Dextromethlorphan	Norethindrone	Uric acid
Diclolrfenac	D-Norpropoxyphene	Verapamil
Diflunisal	Noscapine	Zomepirac
Diaoxin	D.L-Octopamine	
Diphenhydramine	Oxalic acid	

f. Specificity/Cross-Reactivity

To test the specificity/cross-reactivity, drug metabolites and other components that are likely to be present in urine samples were tested. Compounds that produced positive results are listed below.

Morphine, Cutoff=2000 ng/mL	Result Positive at 2,000 ng/mL	%Cross-Reactivity 100%
Codeine	Positive at 2,000 ng/mL	100%
Ethylmorphine	Positive at 5,000 ng/mL	40%
Hydrocodone	Positive at 12,500 ng/mL	16%
Hydromorphine	Positive at 5,000 ng/mL	40%
Levorphanol	Positive at 75,000 ng/mL	2.7%
σ-Monoacetylmorphine	Positive at 5,000 ng/mL	40%
Morphine 3-b-D-glucuronide	Positive at 2,000 ng/mL	100%
Norcodeine	Positive at 12,500 ng/mL	16%
Normorphone	Positive at 50,000 ng/mL	4%
Oxycodone	Positive at 25,000 ng/mL	8%
Oxymorphone	Positive at 25,000 ng/mL	8%
Procaine	Positive at 150,000 ng/mL	1.3%
Thebaine	Positive at 100,000 ng/mL	2%

Oxazepam, Cutoff=300 ng/mL	Result Positive at 300 ng/mL	%Cross-Reactivity 100%
Alprazolam	Positive at 200 ng/mL	150%
a-Hydroxyalprazolam	Positive at 1,500 ng/mL	20%
Bromazepam	Positive at 1,500 ng/mL	20%
Chlordiazepoxide	Positive at 1,500 ng/mL	20%
Clonazepam HCl	Positive at 800 ng/mL	37.5%
Clobazam	Positive at 100 ng/mL	300%
Clonazepam	Positive at 800 ng/mL	37.5%
Clorazepate dipotassium	Positive at 200 ng/mL	150%
Delorazepam	Positive at 1,500 ng/mL	20%
Desalkylflurazepam	Positive at 400 ng/mL	75%
Diazepam	Positive at 200 ng/mL	150%
Estazolam	Positive at 2,500 ng/mL	12%
Flunitrazepam	Positive at 400 ng/mL	75%
D,L-Lorazepam	Positive at 1,500 ng/mL	20%
Midazolam	Positive at 12,500 ng/mL	2.4%
Nitrazepam	Positive at 100 ng/mL	300%
Norchlordiazepoxide	Positive at 200 ng/mL	150%
Nordiazepam	Positive at 400 ng/mL	75%
Temazepam	Positive at 100 ng/mL	300%
Trazolam	Positive at 2,500 ng/mL	12%

g. Effects of Urine Density and pH

Density (Specific Gravity)

12 urine samples with density ranges (1.000-1.035) are collected and spiked with each drug at 25% below and 25% above cutoff levels. Each sample was tested by three batches of CR3 Keyless Split Sample Cup Morphine-Oxazepam. It shows that urine density does not affect test results.

Effect of Urine pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with each drug at 25% below and 25% above cutoff levels. Each sample was tested by three batches of CR3 Keyless Split Sample Cup Morphine-Oxazepam. It shows that urine pH does not interfere with the performance of the test.

2. Comparison Studies

The method comparison for the CR3 Keyless Split Sample Cup Morphine-Oxazepam was performed in-house with three laboratory assistants with relevant experience and a lay person with no experience other than reading the instructions for use. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the table below:

Morphine

Group / Operators		**Negative**	**Low Negative by GC/MS (less than -50%)**	**Near Cutoff Negative by GC/MS (Between -50% and cutoff)**	**Near Cutoff Positive by GC/MS (Between the cutoff and +50%)**	**High Positive by GC/MS (greater than +50%)**
Viewer A	Positive	0	0	2	19	20
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	3	18	20
	Negative	10	20	7	2	0
Viewer C	Positive	0	0	2	18	20
	Negative	10	20	8	2	0
Lay Person	Positive	0	0	3	18	20
	Negative	10	20	7	2	0

Discordant table:

Viewer	Sample number	GC/MS result	Viewer result
Viewer A	OPIC1061	1997	positive
Viewer A	OPIC1064	1994	positive
Viewer A	OPIC1065	2025	negative
Viewer B	OPIC1061	1997	positive
Viewer B	OPIC1062	1943	positive
Viewer B	OPIC1063	2043	negative
Viewer B	OPIC1064	1994	positive
Viewer B	OPIC1065	2025	negative
Viewer C	OPIC1061	1997	positive

Viewer C	OPIC1063	2043	negative
Viewer C	OPIC1064	1994	positive
Viewer C	OPIC1065	2025	negative
Lay person	OPIC1061	1997	positive
Lay person	OPIC1062	1943	positive
Lay person	OPIC1063	2043	negative
Lay person	OPIC1064	1994	positive
Lay person	OPIC1065	2025	negative

Oxazepam

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	17	21
	Negative	10	10	18	2	0
Viewer B	Positive	0	0	3	18	21
	Negative	10	10	17	1	0
Viewer C	Positive	0	0	2	16	21
	Negative	10	10	18	3	0
Lay Person	Positive	0	0	3	15	21
	Negative	10	10	17	4	0

Discordant table:

Viewer	Sample number	GC/MS result	viewer results
Viewer A	BZOC1062	291	positive
Viewer A	BZOC1064	296	positive
Viewer A	BZOC1093	358	negative
Viewer A	BZOC1095	344	negative
Viewer B	BZOC1062	291	positive
Viewer B	BZOC1063	312	negative
Viewer B	BZOC1064	296	positive
Viewer B	BZOC1065	288	positive
Viewer C	BZOC1063	312	negative
Viewer C	BZOC1064	296	positive
Viewer C	BZOC1065	288	positive
Viewer C	BZOC1092	357	negative
Viewer C	BZOC1093	358	negative
Viewer C	BZOC1095	344	negative
Lay Person	BZOC1062	291	positive
Lay person	BZOC1064	296	positive
Lay person	BZOC1065	288	positive

Lay Person	BZOC1063	312	negative
Lay Person	BZOC1092	357	negative
Lay Person	BZOC1093	358	negative
Lay Person	BZOC1095	344	negative

Lay-user study

A lay user study was performed at three intended user sites with 260 lay persons. Participants in the study were 79 males and 47 females tested the Morphine samples, 74 males and 60 females tested the Oxazepam samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled samples and a device. The results are summarized below.

Cup format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
Drug -free	-100%	20	20	0	100%
Morphine	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Oxazepam	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

3. Clinical Studies

   Not applicable

11. Conclusion

    Based on the test principle and performance characteristics of the device, it's concluded that CR3 Keyless Split Sample Cup Morphine-Oxazepam is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2014

GUANGZHOU WONDFO BIOTECH CO., LTD.
C/O JOE SHIA
504 EAST DIAMOND AVE.
SUITE F
GAITHERSBURG MD 20878

Re: K140089
Trade/Device Name: CR3 Keyless Split Sample Cup Morphine-Oxazepam
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, JXM
Dated: January 06, 2014
Received: January 14, 2014

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140089

Device Name
CR3 Keyless Split Sample Cup Morphine-Oxazepam

Indications for Use *(Describe)*
CR3 Keyless Split Sample Cup Morphine-Oxazepam is a rapid test for the qualitative detection of Morphine (a drug in the opiate class) and Oxazepam(a drug in the benzodiazepine class) in human urine at a cutoff concentration of 2000ng/mL and 300ng/mL, respectively.

The tests may yield preliminary positive results even when prescription drugs including Morphine and Oxazepam are ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized cutoff concentration levels for morphine and oxazepam in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Avis T. Danishefsky -S